IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

DONNA BROWN AND EDWARD BROWN	)	
Plaintiffs,	)	
v.	)	**CASE NO.:**
NOVARTIS PHARMACETUICALS CORPORATION,	)	
Defendant.	)	

COMPLAINT

STATEMENT OF JURISDICTION

This Court has jurisdiction over this matter pursuant to 28 U.S.C. Section 1332, for diversity of citizenship and Plaintiff claims an amount in controversy exceeding $75,000.00.

PARTIES

1. Plaintiff, Donna Brown, is over the age of 19 years, and is a resident citizen of Penns Grove, New Jersey. Donna Brown was diagnosed with osteonecrosis of the jaw after using the drug, Aredia©.

2. Plaintiff, Edward Brown, is over the age of 19 years, and is a resident citizen of Penns Grove, New Jersey. Edward Brown is Donna Brown's spouse.

3. Defendant, Novartis Pharmaceuticals Corporation, (hereinafter "Novartis") is a corporation of the state of Delaware, with its principal place of business in New Jersey. At all relevant times herein, Novartis was in the business of promoting, manufacturing and distributing

Aredia©. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold Aredia© in New Jersey, Alabama and throughout the United States.

FACTS

4. This action arises from the use of Aredia©, a medication used in the inhibition of bone resorption.

5. Defendant, Novartis, obtained FDA approval on Aredia© and began its distribution and sale throughout the United States. Aredia© is a brand name used by Novartis to market and distribute Pamidronate Disodium.

6. Plaintiff, Donna Brown, was prescribed Aredia© as a post-cancer treatment of bone loss and osteoporosis. Plaintiff received injections of Aredia© as recommended by her physician.

7. After using Aredia©, Plaintiff, Donna Brown, was diagnosed with osteonecrosis of the jaw.

COUNT ONE

Strict Liability

8. Plaintiffs adopt and incorporate by reference all the above allegations.

9. At all times material hereto, the Defendant has engaged in the business of selling, distributing, manufacturing, marketing and promoting Aredia©, which is unreasonably dangerous, and therefore defective. This product was defective because it was more dangerous than would be reasonably contemplated by the ordinary user.

10. At all times material hereto, Aredia© reached the Plaintiff without substantial change in the condition in which it left the possession of the Defendant.

11. Aredia© medication was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff because:

a. Aredia© contained manufacturing defects in that it can cause osteonecrosis of the jaw.

b. Aredia© was not safe as designed, taking into account that the foreseeable risks involved in its use outweighed its utility and therapeutic benefits.

c. Aredia© was marketed and promoted for use as a prescription for prevention and treatment of bone loss, when it carried an unreasonable and unnecessary risk of serious injury. The risk of harm far outweighed the benefit of use.

d. Aredia© was insufficiently and inadequately tested, yet Defendant promoted it as being pharmaceutically tested and safe for use.

e. Aredia© was not safe due to inadequate and defective instructions and warnings at the time it left the possession of the Defendant. The warnings were inadequate to fully apprise the user and health care providers of the full nature and extent of the risks and dangerous side effects associated with the use;

f. Aredia© was marketed and promoted for use as safe treatment and prevention of bone loss, when it was not.

12. As a direct and proximate result of the actions and inactions of the Defendant as set forth above, the Plaintiffs have sustained injuries and are entitled to damages enumerated below. The Plaintiffs' damages were not caused by an inherent characteristic of the product that cannot be eliminated, but instead were caused by the product being dangerously defective as outlined above.

13. Defendant's actions and inactions as set forth above were intentional and deliberate, and the Plaintiffs are entitled to punitive damages.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiffs demand judgment of the Defendant, Novartis Pharmaceuticals Corporation, for compensatory and punitive damages in an amount determined by the jury to be necessary and just.

COUNT TWO

Failure to Warn

14. Plaintiffs adopt and incorporate by reference all the above allegations.

15. Aredia© can be unreasonably dangerous, even when used for its intended purpose.

16. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks and side effects of Aredia©.

17. Plaintiffs did not have the same knowledge as Defendant and no adequate warning was communicated to Plaintiffs.

18. Defendant had a continuing duty to warn consumers, including the Plaintiffs, of its product, and the risks and dangers associated with it, and negligently and/or wantonly breached its duty as follows:

a. Failed to include adequate warnings with the medications that would alert consumers to the dangerous risks and serious side effects of Aredia©.

b. Failed to provide adequate post-marketing warnings and instructions after the Defendant knew or should have known of the significant risks of osteonecrosis of the jaw from the use of Aredia©.

c. Failed to inform Plaintiffs that Aredia© had not been adequately and thoroughly tested for safety as an inhibitor of bone resorption.

19. As a direct and proximate result of the actions and inactions of the Defendant as set forth above, the Plaintiffs have sustained injuries and damages as listed below.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiffs demand judgment of the Defendant, Novartis Pharmaceuticals Corporation, for compensatory and punitive damages in an amount determined by the jury to be necessary and just.

COUNT THREE

Breach of Warranty of Merchantability

20. Plaintiffs adopt and incorporate by reference all the above allegations.

21. When Defendant placed Aredia© into the stream of commerce, it knew that it would be used as a treatment and prevention of bone loss, and expressly and impliedly warranted to the Plaintiffs that use of Aredia© was a safe and acceptable means of treating and preventing bone loss.

22. Plaintiffs reasonably relied upon the expertise, skill, judgment and knowledge of the Defendant and upon the express and/or implied warranty that Aredia© was of merchantable quality and fit for use to treat bone loss.

23. In fact, Aredia© was not of merchantable quality and was not safe or fit for its intended use because it was unreasonably dangerous and unfit for the ordinary purposes for which it is used, in that Aredia© caused serious injuries and damages. The medication breached the warranties because it was unduly dangerous in expected use and did cause undue injuries to the Plaintiff.

24. As a direct and proximate result of the breach of warranties by the Defendant the Plaintiffs have sustained injuries and damages as set forth below.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiffs demand judgment of the Defendant, Novartis Pharmaceuticals Corporation, for compensatory damages in an amount determined by the jury to be necessary and just.

COUNT FOUR

Negligence

25. Plaintiffs adopt and incorporate by reference all the allegations above.

26. Defendant negligently manufactured, designed, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold Aredia©, in the state of New Jersey, Alabama and throughout the United States.

27. At all times material hereto, Defendant had a duty to exercise reasonable care in the design, manufacture, research and development, testing, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of its medications.

28. Defendant breached its duty and was negligent in its actions, misrepresentations, and omissions toward the Plaintiffs in the following ways:

a. Failing to test and inspect Aredia© in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which is was designed, manufactured, and sold;

b. Failing to utilize and implement a reasonably safe design in the manufacture of Aredia©;

c. Failing to manufacture Aredia© in a reasonably safe condition;

d. Failing to warn the Plaintiffs of the danger of bisphosphonate-induced osteonecrosis;

e. Failing to label Aredia© reasonably so as to warn the Plaintiffs of the danger of bisphosphonate induced osteonecrosis; and

f. Manufacturing Aredia©, which is an unreasonably dangerous / defective drug.

29. Defendant knew or should have known that Aredia© had unreasonably dangerous risks and caused serious side effects of which the Plaintiffs would not be aware. Defendant nevertheless advertised, marketed, sold and distributed the medicine knowing that there were safer methods and products for treatment and prevention of bone loss.

30. Furthermore, Novartis is guilty of negligence *per se*. Novartis violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*, and the Sherman Food, Drug and Cosmetic Law, as well as other applicable laws, statutes, and regulations. Novartis' acts and omissions constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §331. This is negligence *per se*.

31. Novartis failed to meet the standard of care set forth by the following statutes and regulations. Legislators enacted these statutes and regulations for the benefit of a specific class of citizens. The Plaintiffs are part of this class. Therefore, Novartis is negligent *per se* in the following respects:

a. The labeling lacked adequate information on the use of the drugs Aredia© (21 C.F.R. Section 201.56[a] and [d]);

b. The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitations, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable

evidence of their association with the drugs (21 C.F.R. 201.57[e]);

c. There was inadequate information for patients for the safe and effective use of Novartis' drugs (21 C.F.R. 201.57[f][2]);

d. There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Novartis' drugs (21 C.F.R.201.57[f][2]); and

e. The labeling was misleading and promotional (21 C.F.R. 201.56[b]).

32. As a direct and proximate result of the negligent actions and inactions of the Defendant as set forth above, the Plaintiffs have sustained injuries and damages as set forth below.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiffs demand judgment of the Defendant, Novartis Pharmaceuticals Corporation, for compensatory damages in an amount determined by the jury to be necessary and just.

COUNT FIVE

Wantonness

33. Plaintiffs adopt and incorporate by reference all the allegations above.

34. Defendant wantonly and recklessly manufactured, designed, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold Aredia©, in the state of New Jersey, Alabama and throughout the United States.

35. At all times material hereto, Defendant had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of Aredia©.

36. Defendant breached its duty and was wanton and reckless in its actions, misrepresentations, and omissions toward Plaintiffs in the following ways:

a. Failed to test Aredia© which, if properly performed, would have shown that Aredia© had serious side effects, including, but not limited to, osteonecrosis of the jaw;

b. Failed to give full and adequate warnings and instructions with Aredia©.

c. Failed to design and manufacture a treatment for bone loss safe for its intended use.

d. Failed to truthfully market and promote Aredia©.

37. Defendant knew that Aredia© had unreasonably dangerous risks and caused serious side effects of which the Plaintiff would not be aware. Defendant nevertheless advertised, marketed, sold and distributed the medicine knowing that there were safer methods and products for treatment and prevention of bone loss.

38. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendant as set forth above, the Plaintiffs have sustained injuries and damages as set forth below.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiffs demand judgment of the Defendant, Novartis Pharmaceuticals Corporation, for compensatory and punitive damages in an amount determined by the jury to be necessary and just.

COUNT SIX

Fraud, Misrepresentation and Suppression

39. Plaintiffs adopt and incorporate by reference all the allegations above.

40. Defendant fraudulently, intentionally and/or negligently misrepresented to the Plaintiffs, the FDA, and general public, the safety of Aredia© and/or fraudulently, intentionally and/or negligently concealed material including adverse information regarding the safety of Aredia©.

41. Defendant made misrepresentations and actively concealed adverse information at a time when the Defendant knew, or should have known, that Aredia© had defects, dangers, and characteristics that were other than what the Defendant had represented to the FDA, and the consuming public, including the Plaintiffs. Specifically, the Defendant misrepresented to the Plaintiffs, the FDA, and the consuming public that:

a. Aredia©, when used as recommended, was safe for treatment and prevention of bone loss.

b. Aredia© was fully and adequately tested.

d. Aredia© had no serious adverse bone effects.

e. Aredia© was safe and effective.

42. Defendant knew or should have known that these representations were false and that the Plaintiffs would rely on them, leading to the use of Aredia©. Defendant knew that physicians had been told the same false and fraudulent information about Aredia©, and that the Plaintiffs and the prescribing physicians would be relying on information, advertisements and statements made by Defendant about the use, safety and efficacy of Aredia©.

43. At the time of Defendant's fraudulent misrepresentations and active concealment, the Plaintiffs were unaware of the falsity of the statements being made and believed them to be true.

44. The Plaintiffs justifiably relied on and/or were induced by the misrepresentations made by Defendant of the safety and use of Aredia©, and in fact, used Aredia© as recommended.

45. Defendant concealed the truth from the Plaintiffs and the consuming public about the real safety and risks of Aredia©.

46. Defendant had a post-sale duty to warn the Plaintiffs and the public about the potential risks and complications associated with Aredia© in a timely manner.

47. The misrepresentations and active concealment by the Defendant constitutes a continuing tort against the Plaintiffs.

48. As a direct and proximate result of the misrepresentations and concealment of the Defendant as set forth above, the Plaintiffs have sustained injuries and damages set forth below.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiffs demand judgment of Defendant, Novartis Pharmaceuticals Corporation, for compensatory and punitive damages in an amount determined by the jury to be necessary and just.

COUNT SEVEN

Loss of Consortium

49. Plaintiffs hereby adopt and incorporate by reference all the above allegations and further aver as follows:

50. As a direct and proximate result of the negligent and/or wantonness of Novartis as discussed above, Plaintiff, Edward Brown, was caused to lose the consortium and society of his spouse, Donna Brown.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiffs demand judgment of the Defendant, Novartis Pharmaceuticals Corporation, for compensatory and punitive damages in an amount determined by the jury to be necessary and just.

CLAIM FOR DAMAGES

Plaintiffs, Donna Brown and Edward Brown, have sustained injuries and damages, and do make a claim for these:

a. Reasonable and necessary health care expenses incurred in the past;

b. Reasonable and necessary health care expenses which will be incurred in the future;

c. Physical pain and suffering in the past;

d. Physical pain and suffering which will be endured in the future;

e. Mental anguish suffered in the past;

f. Mental anguish which will be endured in the future;

g. Physical disability and impairment, past and future;

h. All other incidental and consequential damages, fees and expenses.

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PLAINTIFF DEMANDS A TRIAL OF ALL ISSUES BY STRUCK JURY.

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